Kvick Lab™ Cassette Holder II

User Manual

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1 Introduction

About this chapter

This chapter contains important user information, descriptions of safety notices, regulatory information, and intended use of Kvick Lab Cassette Holder II.

In this chapter

This chapter contains the following sections:

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1.1 About this manual	6
1.2 Important user information	7
1.3 Regulatory information	9

1.1 About this manual

Purpose of this document

The *User Manual* provides you with the instructions you need to use Kvick Lab Cassette Holder II.

Scope of this document

This manual is valid for Kvick Lab Cassette Holder II. Detailed information regarding cassettes or filtration systems is not covered.

More information

More information related to the use of Kvick Lab Cassette Holder II can be found in the following documents:

- *ÄKTA flux 6* Operating Instructions, article number 29-0468-96
- *Cross flow filtration Method Handbook*, article number 29-0850-76
- *Kvick Lab and Kvick Flow Cassettes User Manual*, article number 18-1171-69

1.2 Important user information

Read this before using Kvick Lab Cassette Holder II

All users must read the entire *User Manual* before installing, using or maintaining the cassette holder.

Always keep the *User Manual* at hand when using Kvick Lab Cassette Holder II.

Do not use Kvick Lab Cassette Holder II in any other way than described in the user documentation. If you do, you may be exposed to hazards that can lead to personal injury, you may cause damage to the equipment, and no warranty will apply.

Intended use of Kvick Lab Cassette Holder II

The Kvick Lab Cassette Holder II is designed to be used with one to five filter cassettes for cross flow membrane separations, with a cross flow rate of 600 to 800 ml/min/per 0.11 m^2 cassette.

WARNING

Do not use Kvick Lab Cassette Holder II in any other way than described in Kvick Lab Cassette Holder II user manual.

Prerequisites

In order to use Kvick Lab Cassette Holder II safely and according to the intended purpose, the following prerequisites must be met:

- You should be acquainted with the use of general bioprocessing equipment and with handling of biological materials.
- You must read and understand the Safety chapter of this *User Manual*.
- The Kvick Lab Cassette Holder II must be installed according to the instructions in *Chapter 5 Installation, on page 21*.

Safety notices

This user documentation contains safety notices (WARNING, CAUTION, and NOTICE) concerning the safe use of the product. See definitions below.

WARNING

WARNING indicates a hazardous situation which, if not avoided, could result in death or serious injury. It is important not to proceed until all stated conditions are met and clearly understood.

CAUTION

CAUTION indicates a hazardous situation which, if not avoided, could result in minor or moderate injury. It is important not to proceed until all stated conditions are met and clearly understood.

NOTICE

NOTICE indicates instructions that must be followed to avoid damage to the product or other equipment.

Notes and tips

Note: *A note is used to indicate information that is important for trouble-free and optimal use of the product.*

Tip: *A tip contains useful information that can improve or optimize your procedures.*

1.3 Regulatory information

Regulatory compliance

This product fulfils the following requirements:

Standard	Description
USP class VI, EN 10204 2.1	The tested materials have been tested for process wetted and pressure retaining polymers and elastomers.
CFR 177	The material is in compliance with Code of Federal Regulations (CFR), Food and Drugs Title 21, Part 177 FDA.
AFO	Animal free origin, alt. EMEA/410/01 compliant The polymeric material is in accordance with the conditions for tallow derivates in the CPMP Note for Guidance (EMA/410/01 Rev. 3) and therefore BSE/TSE contamination is unlikely. Where an absolutely animal free claim can not be made, a statement to confirm that a component is free from BSE/TSE infectious prions is not scientifically possible.

2 Safety instructions

About this chapter

This chapter describes safety precautions for Kvick Lab Cassette Holder II. Recycling is also described.

Important

WARNING

Before installing, operating or maintaining Kvick Lab Cassette Holder II, all users must read and understand the entire contents of this chapter to become aware of the hazards involved.

Failure to do this may cause human injury or death, or damage to the equipment.

In this chapter

This chapter contains the following sections:

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2.1 Safety precautions	11
2.2 Recycling information	14

2.1 Safety precautions

Introduction

The safety precautions in this section are grouped in the following categories:

- *General precautions, on page 11*
- *Personal protection, on page 12*
- *Installing and moving, on page 12*
- *System operation, on page 12*
- *Maintenance, on page 13*

General precautions

WARNING

The customer must make sure installation, maintenance, operation and inspection is carried out by qualified personnel who are adequately trained, understand and adhere to local regulations and the user manual, and have a thorough knowledge of Kvick Lab Cassette Holder II and the entire process.

WARNING

Do not operate the product in any other way than described in the Kvick Lab Cassette Holder II user manual.

CAUTION

If Kvick Lab Cassette Holder II leaks, it can release potentially hazardous process fluids, causing bodily harm. Make sure that the pressure limit is set to the specified maximum pressure of the filter. Periodically check parts for wear and make sure components are assembled correctly.

Personal protection

WARNING

Always use appropriate Personal Protective Equipment (PPE) during installation and maintenance of Kvick Lab Cassette Holder II.

Installing and moving

WARNING

Before removing the Kvick Lab Cassette Holder II from the filtration system, make sure that the flow path of the filter and the filter holder is emptied and depressurized to an appropriate level for safe handling.

CAUTION

Because of the weight of the Kvick Lab Cassette Holder II, great care must be taken not to cause squeezing or crushing injuries during movement. To prevent injury from dropping a cassette holder on your feet or hands, make sure you have a secure, controlled grip, or the proper equipment to move the cassette holder.

Wear safety shoes.

System operation

WARNING

Before connecting the filter to Kvick Lab Cassette Holder II, read the instructions for use of the filter. To avoid exposing the filter to excessive pressure, make sure that the pressure limit is set to the specified maximum pressure of the filter.

Maintenance

WARNING

Before any maintenance or decommissioning work is performed on Kvick Lab Cassette Holder II, make sure that the holder:

- is empty and depressurized.
- is disconnected from process feed.

Also make sure that all process wetted areas are clean and decontaminated.

2.2 Recycling information

Introduction

This section contains information about the decommissioning of Kvick Lab Cassette Holder II.

Decontamination

Kvick Lab Cassette Holder II shall be decontaminated before decommissioning and all local regulations shall be followed with regard to scrapping of the equipment.

Disposal, general instructions

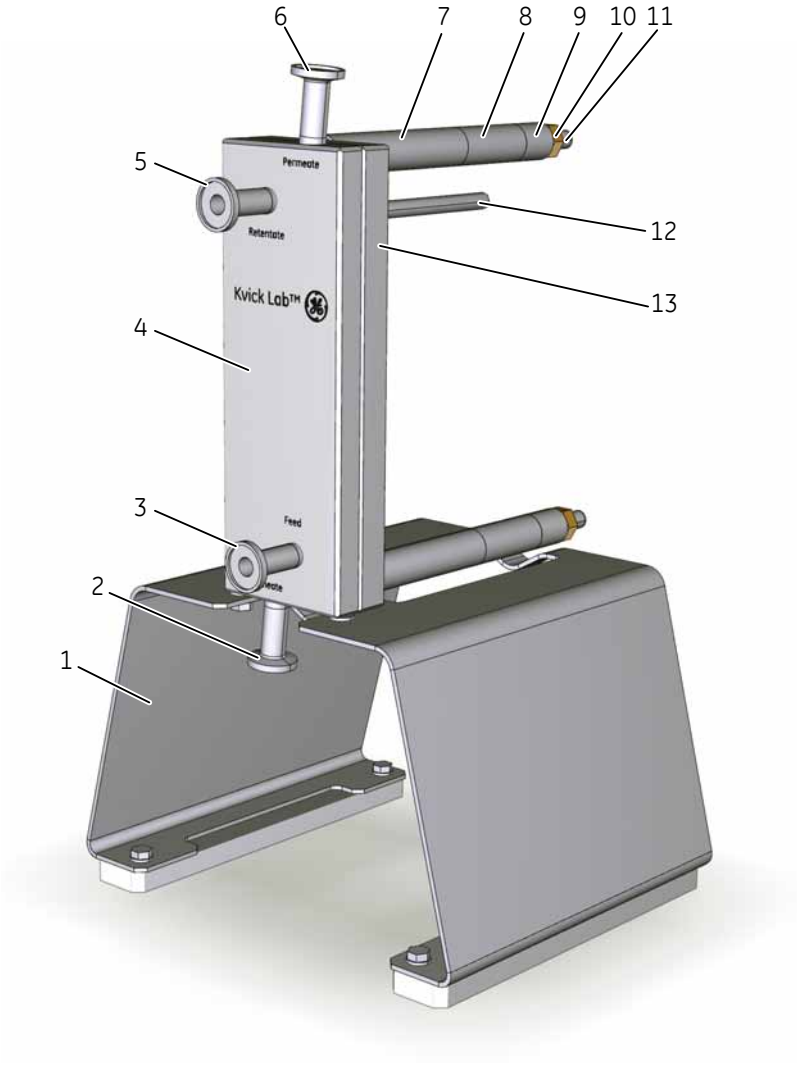
When taking Kvick Lab Cassette Holder II out of service, the different materials must be separated and recycled according to national and local environmental regulations.

3 Kvick Lab Cassette Holder II overview

About this chapter

This chapter provides an overview of Kvick Lab Cassette Holder II parts.

Kvick Lab Cassette Holder II illustration



Part	Function
1	Stand
2	**Permeate** (drainage) port
3	**Feed** port
4	Flow distribution manifold
5	**Retentate** port
6	**Permeate** port
7	Spacer 100 mm
8	Spacer 50 mm
9	Spacer 25 mm
10	Nut and washer
11	Tie rod
12	Guide rod
13	Back plate

Cassettes and spacers

Spacers with three different lengths, 25, 50 and 100 mm are supplied with the holder. The spacers enable that up to five Kvick Lab cassettes can be installed in the holder.

Guide rods

Two guide rods, with the diameters 9 and 6 mm, are delivered with the holder. The 9 mm guide rod is suitable for Kvick Lab cassettes, and the other may be suitable for other brands.

4 Unpacking

About this chapter

This chapter describes the contents of the delivery package and how to unpack the Kvick Lab Cassette Holder II.

Safety precautions

CAUTION

Because of the weight of the Kvick Lab Cassette Holder II, great care must be taken not to cause squeezing or crushing injuries during movement. To prevent injury from dropping a cassette holder on your feet or hands, make sure you have a secure, controlled grip, or the proper equipment to move the cassette holder.

Wear safety shoes.

Package contents

Each shipment of a Kvick Lab Cassette Holder II includes the following components:

- Kvick Lab Cassette Holder II
- Cleaning-In-Place (CIP) cassette
- two gaskets for filter cassettes
- torque wrench and socket
- four TC gaskets
- four TC clamps
- stopper plug
- user manual

Visual inspection

Check:

- that all equipment is enclosed in the box according to the packing list.
- the equipment for any apparent damage and document carefully, if found.

If any equipment is missing or damage is found, contact your GE representative immediately.

Unpacking the Kvick Lab Cassette Holder II

Follow the general unpacking instructions below to unpack the filter holder.

Step	Action
1	Place the box on the floor.
2	Open the top of the box and remove the foam insert.
3	Remove the accessories and the user manual.
4	Lift Kvick Lab Cassette Holder II and place it on a laboratory bench.

5 Installation

About this chapter

This chapter describes how to install the Kvick Lab Cassette Holder II.

In this chapter

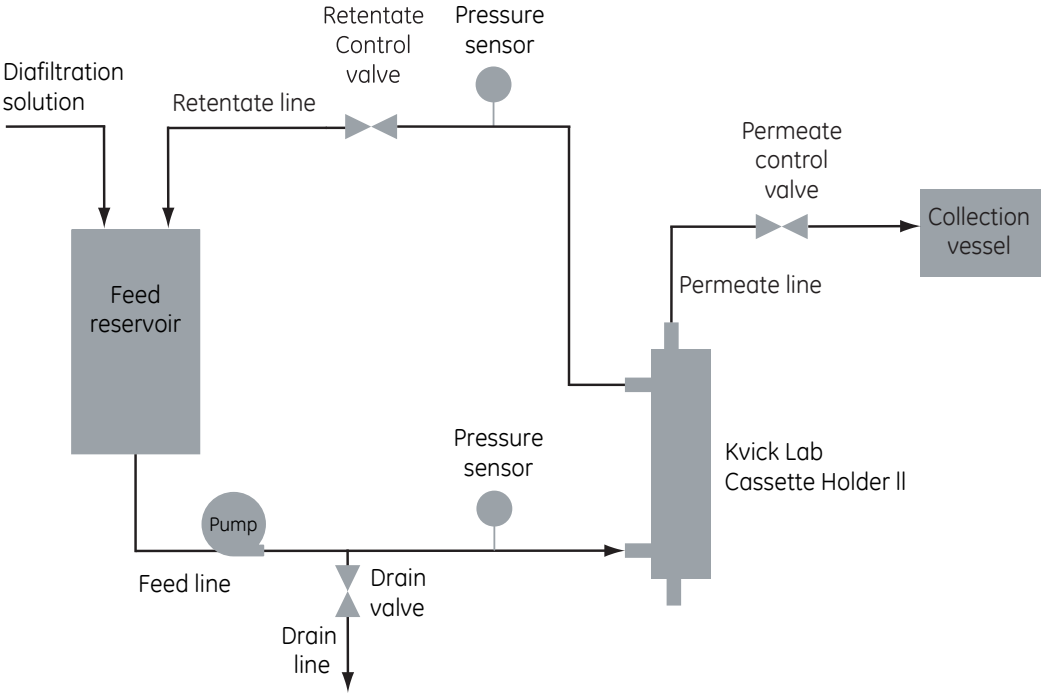
This chapter contains the following sections:

Section	See page
5.1 Installation of Kvick Lab holder ll	22
5.2 Installation of cassettes	24

5.1 Installation of Kvick Lab holder II

Where to install the holder

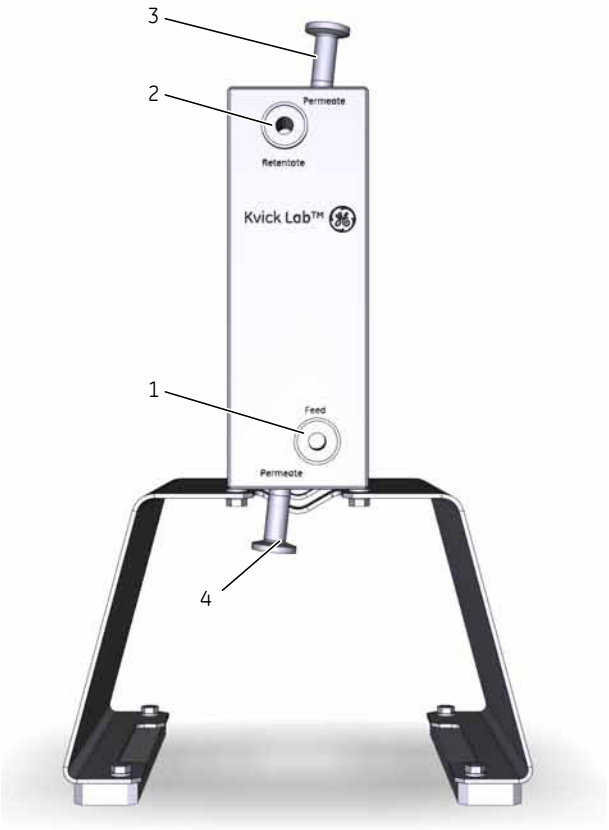
The integration of the cassette holder into your cross-flow system depends upon your application and filtration goals. The image below shows a basic example cross-flow configuration. To learn about alternate system configurations for special applications, contact your GE representative.



Installation

Follow these steps to install the Kvick Lab Cassette Holder II in the cross-flow system:

Note: *Keep tubing short to minimize holdup volume.*



Step	Action
1	Place Kvick Lab Cassette Holder II next to your cross-flow system.
2	Connect the holder's feed port (1), to the feed line tubing using a TC gasket and a TC clamp.
3	Connect the holder's retentate port (2), to the retentate line tubing using a TC gasket and a TC clamp.
4	Connect the holder's upper permeate port (3), to the permeate line tubing using a TC gasket and a TC clamp.
5	Attach the stopper plug to the holder's lower permeate port (4). The port can be used for drainage, in such case connect a valve to the lower port.

5.2 Installation of cassettes

Safety precautions

WARNING

Before connecting the filter to Kvick Lab Cassette Holder II, read the instructions for use of the filter. To avoid exposing the filter to excessive pressure, make sure that the pressure limit is set to the specified maximum pressure of the filter.

Cassette types

Kvick Lab Cassette Holder II can hold multiple cassettes depending upon the cassette type and the membrane area the application requires. The table below describes the available cassette types and the torque required to install the cassettes in the holder.

Note: *The cassette holder follow industry standard cassette dimensions and accepts other cassettes of standard layout*.

Cassette types	Cassette size	Number of cassettes	Nut torque
Kvick Lab	0.11 m^2 (1.2 ft^2)	1 to 5	20.3 Nm (180 lb-in)

Prepare the cassette(s)

Unpack and prepare the cassette(s) for use according to the manufacturer's instructions.

Prepare the holder

Follow these steps to prepare the holder for insertion of the cassettes.

Step	Action
1	Remove the nuts and washers.

2	Remove the spacers.

Step	Action
3	Slide the back plate away from the flow distribution manifold.

Insert the cassette(s)

Follow these steps to insert the cassette(s) into the holder.

Step	Action
1	Check that a guide rod of the correct size is used. If not, change the guide rod to a fitting size. ***Note:*** *To loosen the guide rod, turn it anti-clockwise. To fasten the guide rod, turn it clockwise.*
2	Clean and wet a gasket by rinsing it with distilled (DI) water, or water-for-injection (WFI).

Step	Action
3	Place the filter gasket against the back plate, aligning the holes in the gasket with the holes in the back plate.

Result: The gasket will stick to the manifold.

Note:

If a cassette is used without built-in gaskets; gaskets need to be placed at the distribution plate and between the cassettes.

Step	Action
4	Place the cassette into the holder with the gasket-side of the cassette facing the flow distribution manifold, and slide the cassette against the flow distribution manifold.

Repeat this step, to install two or more cassettes.

Step	Action
5	Slide the back plate forward to hold the cassettes in place. Make sure that the holes in the manifold, gasket, and cassettes line up.

6	Add spacers to the tie rods until about 16 mm (0.75-inches) of the threads are exposed on each tie rod.
7	Reinstall the washers and nuts. Tighten the nuts by hand.

Step	Action
8	Using the supplied torque wrench and socket, tighten each nut alternately, 1/4 turn at a time, until each nut has been tighten to a torque of 20.3 Nm for Kvick Lab cassettes. ***Note:*** *The torque value is depending on the cassette type used.*

Final considerations before use

Once the cassettes are installed in the holder, the following actions should be taken:

- test the filtration system for possible leakage according to the filtration system's operating instructions
- test the water flux and the integrity of the cassettes according to the cassette's user manuals, for example *Kvick Lab and Kvick Flow Cassettes User Manual*, article no. 18-1171-69.
- make sure that the pressure limits for installed filters are not exceeded

Remove the cassette(s)

WARNING

Before removing the Kvick Lab Cassette Holder II from the filtration system, make sure that the flow path of the filter and the filter holder is emptied and depressurized to an appropriate level for safe handling.

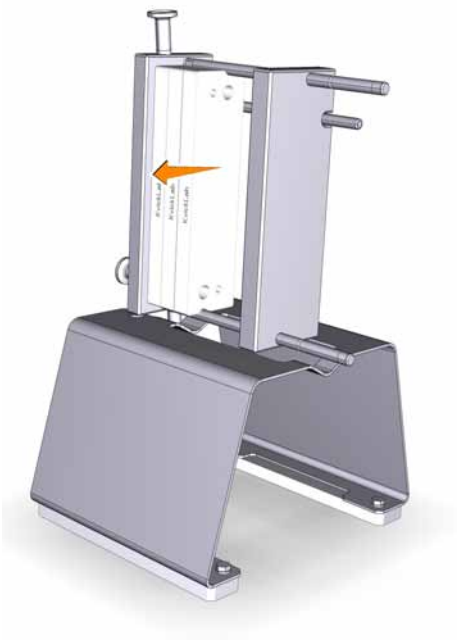
Follow these steps to remove the cassette(s) in the Kvick Lab Cassette Holder II:

Step	Action
1	Remove the nuts and washers.

2	Remove the spacers.

Step	Action
3	Slide the back plate away from the flow distribution manifold.

4	Remove the cassette(s) and the gasket from the holder.



Step	Action
5	Clean the Kvick Lab Cassette Holder II according to the instructions in *Clean the permeate line and the holder, on page 35*.

6 Maintenance

About this chapter

This chapter provides required information to enable users and service personnel to clean and maintain the Kvick Lab Cassette Holder II.

Safety precautions

WARNING

Before any maintenance or decommissioning work is performed on Kvick Lab Cassette Holder II, make sure that the holder:

- is empty and depressurized.
- is disconnected from process feed.

Also make sure that all process wetted areas are clean and decontaminated.

CAUTION

If Kvick Lab Cassette Holder II leaks, it can release potentially hazardous process fluids, causing bodily harm. Make sure that the pressure limit is set to the specified maximum pressure of the filter. Periodically check parts for wear and make sure components are assembled correctly.

Inspection

Make the inspections in the list below periodically, depending on normal or frequent use of Kvick Lab Cassette Holder II. The system owner is solely responsible for establishing applicable routines for periodic maintenance.

Make these inspections:

- Inspect the tie rods and nuts for excessive wear and replace as needed.
- Inspect the mating surfaces of the flow manifold and backing plate for scratches.

- Inspect the TC clamps and TC gaskets for damage or wear, and replace as needed.
- Check the rigidity of the stand. If the stand wobbles, check that the plastic supports are not damaged and the screws are tightened.

If the mating surfaces of the flow manifold and backing plate become excessively scratched, contact your GE representative for assistance.

CIP

Step	Action
1	Place the CIP cassette gasket on the flow distribution manifold.
2	Insert the CIP cassette in the cassette holder the same way as cassettes are inserted in the Kvick Lab Cassette Holder II, refer to *Insert the cassette(s), on page 26*.
3	Clean the system with the CIP cassette installed in the Kvick Lab Cassette Holder II.
4	After CIP, remove the CIP cassette holder the same way as cassettes are removed, refer to *Remove the cassette(s), on page 30*.
5	Remove the CIP cassette gasket.

Clean the permeate line and the holder

Follow the instructions below to clean the permeate line and the holder after use and after CIP.

Step	Action
1	Wash the permeate line with clean water to remove dirt and residual process/cleaning solutions.
2	Wash down the exterior components of Kvick Lab Cassette Holder II with clean water and blow the wash water out of the flow manifold channels with compressed air.
3	Wipe the holder dry with a clean, lint-free cloth.

Storage of Kvick Lab Cassette Holder II

To store the Kvick Lab Cassette Holder II, clean it and place several layers of a clean cloth between the flow manifold and the backing plate. Install the spacers, washers, and nuts, and lightly hand tighten to hold the cloth and backing plate in place. Place the holder in a dry, protected area such as a cabinet to prevent contamination or accidental dropping.

NOTICE

Do not store filter cassettes in Kvick Lab Cassette Holder II.

7 Troubleshooting

About this chapter

This chapter provides information required to enable users to identify and correct problems that may occur when using the Kvick Lab Cassette Holder II.

If the suggested actions in this guide do not solve the problem, or if the problem is not covered by this guide, contact your GE representative for advice.

Troubleshooting guide

The table below describes problems that may occur with Kvick Lab Cassette Holder II, together with possible corrective actions.

Symptom	Possible Cause	Corrective action
Holder leaks from between flow manifold and backing plate	Insufficient clamping force	Check tie rod nut torque
	System is being run at excessive operating pressures	Run system at proper operating pressures
	Cassette gasket damaged or not seated properly	Remove and inspect gasket. Re-install gasket.
	Cassette sealing surfaces damaged	Remove and inspect sealing surfaces on the cassette. Replace cassette if necessary.
	Sealing surface of the flow manifold or backing plate scratched	Inspect sealing surface of flow manifold and backing plate for scratches.
Process solution leaks from sanitary connections	TC clamp connection gasket missing, worn, damaged, improperly mounted, or wrong size	Inspect gasket for wear, damage, and proper sizing. Reinstall gasket.
	TC clamp loose	Tighten TC clamp

Symptom	Possible Cause	Corrective action
Feed pressure is too high	Cassette fouled	Clean cassette
	Obstruction in feed line or retentate line	Inspect lines for obstruction
	Feed inlet in cassette plugged	Switch feed and retentate lines to reverse flow, and flush with DI water or WFI. Retorque tie rod nuts
Kvick Lab Cassette Holder II leaks during integrity testing	Insufficient clamping force	Locate leaking area by feeling air leak with hand, or by applying soapy water and looking for bubbles. Remove, inspect, and reinstall cassette and gasket
	Improperly seated cassette or gasket	
	Sealing surface of holder or cassette damaged	Locate leaking area by feeling air leak with hand, or by applying soapy water and looking for bubbles. Remove cassette and gasket and inspect sealing surface of flow manifold, backing plate, and cassette
	Faulty valve	Check integrity of valves and replace as needed.

8 Reference information

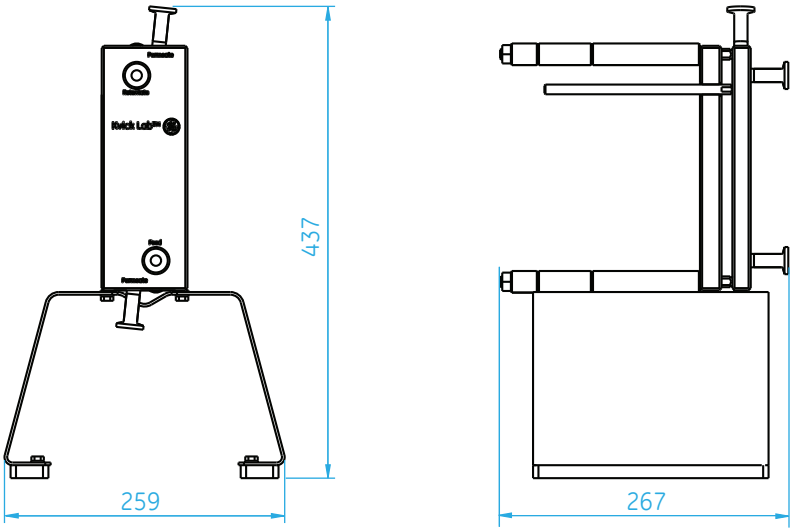
About this chapter

This chapter provides reference information that may become useful when installing, operating, maintaining and troubleshooting Kvick Lab Cassette Holder II.

8.1 Specifications

Dimensions

All dimensions are presented in mm.



Property	Value
Width	259 mm
Deep	267 mm
Height	437 mm

Mechanical data

Property	Value
Weight	7.7 kg
Feed, retentate, and permeate part fittings	1/2" TC

Property	Value
Materials of construction	*Stainless steel:* flow distribution manifold, back plate, tie rods, guide rods, washers, and stand *Bronze:* tie rod nuts
Type and number of cassettes	Kvick Lab – 0.11 m^2 (maximum of 5 cassettes installed)

Capacity

Property	Value
Cross-flow rate	600 to 800 ml/min/per 0.11 m^2 cassette
Recommended operating temperature	-5 to 50°C
Maximum operating temperature	121°C
Maximum operating pressure	4 bar (g)
Operating pH	1 to 14
Cassette holdup volume	20 ml
Hardware holdup volume (feed/retentate)	< 2 ml
Maximum membrane area	0.55 m^2

8.2 Chemical resistance

The table below gives chemicals that may be used with the Kvick Lab Cassette Holder II.

Consult *Kvick Lab and Kvick Flow Cassettes User Manual*, article no. 18-1171-69 for guidelines on the chemical compatibility of cassettes.

Chemical	Concentration	Max time / cycle	Max acc. expos.	Usage
Acetic acid	25%	3 h	3000 h	CIP
Acetone	10%	1 h	N/A	UV cell test
Citric acid	pH 2 to 2.5	1 h at temp ≤ 60°C	1000 h	CIP
Ethanol	20%	12 months	N/A	Storage
Ethanol / Acetic acid	20%	3 h	3000 h	CIP
Guanidine hydrochloride	6 M	5 h	5000 h	CIP
Hydrochloric acid	0.1 M at pH=1	1 h	1000 h	CIP
Phosphoric acid	5%	Overnight	Unlimited	For SS passivation
2-propanol	30%	1 h	1000 h	CIP
Sodium chloride	0 to 3 M	3 h	3000 h	Purification, CIP
Sodium hydroxide	1 M at pH=14 0.5 M 0.01 M at pH=12	24 h at temp ≤40°C 3 h at temp ≤ 60°C 12 months	1000 days 3000 h Unlimited	CIP CIP Storage
Sodium hypochlorite	300 ppm	3 h at temp ≤ 60°C	3000 h	CIP
Sodium hydroxide/Ethanol	1 M or 20%	3 h	3000 h	CIP
Urea	8 M	5 h	5000 h	Purification, CIP
Cleaning solutions	1% to 6% Steris CIP 100™, 0.5% Henkel P3™-11, 0.2% Micro, 0.2% Terg-a-zyme™, 0.1% Tween™ 80	3 h at temp ≤ 60°C	3000 h	CIP

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First published May. 2014.

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29-0271-61 AB 05/2014 a1716